Amendments to the claims:

This listing will replace all prior versions and listings of claims in the application.

1 (currently amended): A method for inducing an antigen- specific immune response comprising:

(a) providing a formulation comprised of at least one antigen and at least one adjuvant, wherein one adjuvant of said at least one adjuvant is bacterial DNA; wherein said at least one antigen or an adjuvant which is not bacterial DNA is provided as at least one polynucleotide encoding said at least one antigen or [an] adjuvant which is not bacterial DNA;

(b) applying said formulation epicutaneously to skin of an organism without passing through the dermis of said skin; wherein said

(c) antigen-specific immune response is induced in said organism.

2 (currently amended): [A] <u>The</u> method of claim 1, wherein the antigen-specific immune response is enhanced as compared to <u>the immune response induced by</u> a formulation that does not contain the adjuvant.

3 (canceled).

4 (previously presented): The method of claim 1, wherein said bacterial DNA is CpG1.

5 –8 (canceled).

9 (previously presented): The method of claim 1 further comprising hydrating the skin.

10 (previously presented): The method of claim 9, wherein hydration enhances the antigen-specific immune response as compared to application of the formulation without hydration.

11 (previously presented): The method of claim 1, wherein a physical, chemical, electrical, or

sonic penetration enhancer is not involved in application of the formulation.

12 (previously presented): The method of claim 1, wherein the formulation does not include a penetration enhancer, viral particle, liposome, proteosome, or chemical transfectant.

13 (canceled).

14 (previously presented): The method of claim 1, wherein the antigen and the adjuvant are provided as separate components of the formulation.

15 - 27 (canceled).

28 (previously presented): The method of claim 1, wherein the organism is a human.

29 (canceled).

30 (previously presented): The method of claim 1, wherein the induced immune response recognizes at least one surface antigen of a pathogen.

31 (previously presented): The method of claim 1, wherein the induced immune response recognizes at least one antigen of at least one pathogen.

32 (currently amended): [A] The method of claim 31, wherein the pathogen is a bacterium.

33 (currently amended): [A] The method of claim 31, wherein the pathogen is a virus.

34 (currently amended): [A] The method of claim 31, wherein the pathogen is a fungus.

35 (previously presented): The method of claim 31, wherein the pathogen is a parasite.

36 (previously presented): The method of claim 1, wherein the induced immune response recognizes at least one protein antigen of a pathogen.

37 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes at least one protein antigen of a bacterium.

38 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes at least one protein antigen of a virus.

39 (previously presented): The method of claim 1, wherein the induced immune response recognizes at least one glycoprotein antigen of a pathogen.

40 (previously presented): The method of claim 1, wherein the induced immune response recognizes at least one lipoprotein antigen of a pathogen.

41 (previously presented): The method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in whole cell form selected from the group consisting of live microbes, attenuated microbes, and inactivated microbes.

42 (currently amended): [A] The method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a viral particle or virion form selected from the group consisting of live viruses, attenuated viruses, and inactivated viruses.

43 (currently amended): [A] The method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a whole-cell form selected from the group consisting of live bacteria, attenuated bacteria, and inactivated bacteria.

44 (previously presented): The method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a cell-free form.

45-46 (canceled).

47 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes an autoantigen.

48 (currently amended): [A] The method of claim 47, wherein the autoantigen-specific immune response provides treatment for at least one autoimmune disease or other autoimmune condition.

49 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes a human autoantigen.

50 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes a tumor antigen.

51 (currently amended): [A] The method of claim 50, wherein the tumor antigen-specific immune response provides treatment for at least one neoplastic disease or other neoplastic condition.

52 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes a human tumor antigen.

53 (currently amended): [A] The method of claim 1, wherein the induced immune response recognizes an allergen.

54 (currently amended): [A] The method of claim 53, wherein the allergen-specific immune response provides treatment for at least one allergy or other allergic condition.

55-61 (canceled).

62 (withdrawn): A method of claim 1, wherein the adjuvant is at least an ADP-ribosylating exotoxin.

63 (withdrawn): A method of claim 62, wherein the ADP-ribosylating exotoxin is genetically modified to be less toxic to the organism than non-modified ADP-ribosylating exotoxin.

64 (withdrawn): A method of claim 1, wherein the adjuvant is at least a cholera toxin.

65 (withdrawn): A method of claim 1, wherein the adjuvant is at least a pertussis toxin.

66 (withdrawn): A method of claim 1, wherein the adjuvant is at least an E. coli heat-labile enterotoxin.

67 (withdrawn): A method of claim 1, wherein the adjuvant is at least a Pseudomonas exotoxin.

68 (withdrawn): A method of claim 1, wherein the adjuvant is at least one pathogen-associated molecular pattern (PAMP).

69 (withdrawn): A method of claim 68, wherein the PAMP is a polynucleotide selected from the group consisting of bacterial deoxyribonucleic acids, unmethylated CpG motifs, and double-stranded ribonucleic acids.

70 (withdrawn): A method of claim 68, wherein the PAMP is selected from the group consisting

of lipopolysaccharides, lipid A, and monophosphoryl lipid A.

71 (withdrawn): A method of claim 1, wherein the adjuvant is at least a chemokine or a cytokine.

72 (withdrawn): The method of claim 1, wherein the adjuvant is provided in a cell-free form.

73 (withdrawn): A method of claim 1, wherein the adjuvant is provided as at least one polynucleotide which encodes at least the adjuvant.

74 (withdrawn): A method of claim 1, wherein the adjuvant is provided as at least one plasmid which encodes at least the adjuvant.

75-79 (canceled).

80 (currently amended): A method for inducing an antigen- specific immune response in an organism comprising:

(a) providing a formulation comprised of at least one antigen and at least one adjuvant, wherein one adjuvant of said at least one adjuvant is bacterial DNA;

wherein said at least one antigen or an adjuvant which is not bacterial DNA is provided as at least one polynucleotide encoding said at least one antigen or adjuvant which is not bacterial DNA and enhancement of said antigen specific immune response by said adjuvant is separable from the antigen-specific immune response induced by an immunogenic epitope of said antigen;

(b) applying said formulation to skin of said organism; wherein said

(c) immune response in said organism specific for said immunogenic epitope ~~which~~ is enhanced as compared to an immune response induced by a formulation that does not contain said adjuvant.

81 (previously presented): The method of claim 80, wherein said bacterial DNA is CpG1.

82-86 (canceled).

87 (previously presented): The method of claim 80, wherein the antigen-specific immune response recognizes at least one pathogen.

88-89 (canceled).

90 (previously presented): The method of claim 80, wherein the organism is a human.

91-92 (canceled).

93 (currently amended): A formulation which comprises:

(a) at least one antigen, and

(b) at least one adjuvant, wherein one adjuvant of said at least one adjuvant is bacterial DNA; wherein said at least one antigen or an adjuvant which is not bacterial DNA is provided as at least one polynucleotide encoding said at least one antigen or adjuvant which is not bacterial DNA, and enhancement of said antigenic immune response by said adjuvant is separable from the antigen specific immune response induced by an immunogenic epitope of said antigen, and said formulation induces an immune response specific for said immunogenic epitope which is enhanced as compared to an immune response induced by a formulation that does not contain said adjuvant.

94 (previously presented): The formulation of claim 93, wherein the formulation is packaged in a form selected from the group consisting of cream, emulsion, gel, lotion, ointment, paste, and suspension.

95 (previously presented): The formulation of claim 93 further provided in a container suitable for immersion or spraying.

96 (previously presented): The formulation of claim 93, wherein said bacterial DNA is CpG1.

97 (canceled).

98 (previously presented): The formulation of claim 93, wherein the formulation consists essentially of the adjuvant and the antigen.

99 (previously presented): The formulation of claim 93, wherein the formulation is packaged in a unit dosage form which is effective to induce said antigen specific immune response.

100-101 (canceled).

102 (previously presented): A method for inducing an immune response in an organism, the method comprising the steps of:

applying topically to skin of the organism an immunogen-encoding polynucleotide in an amount sufficient for uptake by a skin cell and sufficient for expression of the immunogen-encoding polynucleotide and induction of an immune response, wherein the skin to which the polynucleotide is applied comprises hair and is not treated with a chemical or mechanical penetration enhancer, and wherein the polynucleotide is operably linked to a promoter, and is not contained within a viral particle.

103 (previously presented): The method of claim 102, wherein the skin to which the polynucleotide is applied is intact.

104 (previously presented): The method of claim 102, wherein the polynucleotide is free of calcium phosphate.

105 (previously presented): The method of claim 102, wherein the polynucleotide is administered in the absence of an amount of liposomes or cationic lipids effective to facilitate transfection.

106 (previously presented): The method of claim 102, wherein the skin includes epidermis.

107 (previously presented): The method of claim 102, wherein the organism is a mammal.

108 (previously presented): The method of claim 102, wherein the organism is a human.

109 (previously presented): The method of claim 102, wherein the immunogen-encoding polynucleotide is a polynucleotide encoding a polypeptide derived from a pathogen selected from the group consisting of bacterium, fungus, virus, and parasite.

110 (previously presented): A method for inducing an immune response in an organism, the method comprising the steps of:

applying topically to skin of the organism an immunogen-encoding polynucleotide in an amount sufficient for uptake by a skin cell and sufficient for expression of the immunogen-encoding polynucleotide and induction of an immune response, wherein hair is not removed from the skin prior to applying the polynucleotide and the skin is not treated with a chemical or mechanical penetration enhancer, and wherein the polynucleotide is operably linked to a promoter and is not contained within a viral particle.

111 (previously presented): The method of claim 110, wherein the skin includes epidermis.

112 (previously presented): A method for introducing a polynucleotide into a skin cell in vivo for expression of a gene product encoded by the introduced polynucleotide, the method comprising the steps of:

applying topically to skin of a subject a polynucleotide in an amount sufficient for uptake by skin cell and sufficient for expression of a gene product encoded by the polynucleotide to provide in the subject a biological effect associated with gene product expression; wherein the skin to which the polynucleotide is applied comprises hair and is not treated with a chemical or mechanical penetration enhancer, and wherein the polynucleotide is operably linked to a promoter, and is not contained within a viral particle.

113 (previously presented): The method of claim 112, wherein the skin to which the polynucleotide is applied is intact.

114 (previously presented): The method of claim 112, wherein the skin includes epidermis.

115 (previously presented): A method for delivering a polypeptide to an organism, the method comprising the steps of:

applying topically to skin of the organism a polypeptide-encoding polynucleotide in an amount sufficient for uptake by a skin cell and sufficient for expression of the polypeptide to provide in the subject a biological effect associated with polypeptide expression;

wherein the skin to which the polynucleotide is applied comprises hair and is not treated with a chemical or mechanical penetration enhancer, and

wherein the polynucleotide is operably linked to a promoter, and is not contained within a viral particle.

116 (previously presented): The method of claim 115, wherein the polynucleotide is administered in the absence of an amount of liposomes or cationic lipids effective to facilitate transfection.

117 (previously presented): A method of inducing a systemic immune response, comprising topically administering a polynucleotide encoding antigen, adjuvant or both to skin of an organism without penetrating past dermis; wherein an effective amount of the antigen, adjuvant or both is expressed by an operably-linked regulatory region derived from a viral genome to induce said systemic immune response in said organism.

118 (previously presented): The method of claim 117, wherein the polynucleotide is topically administered on shaved skin of said organism.

119 (previously presented): The method of claim 117, wherein the polynucleotide is in a plasmid.

120 (previously presented): The method of claim 117, wherein the operably linked regulatory region is derived from an adenovirus genome.

121 (previously presented): The method of claim 117, wherein the polynucleotide encodes antigen or an immunogenic epitope thereof.

122 (previously presented): The method of claim 117, wherein the antigen or immunogenic epitope thereof is expressed to produce a systemic immune response against a pathogen or cancer.

123 (previously presented): The method of claim 117, wherein the antigen or immunogenic

epitope thereof is expressed to produce a systemic immune response against a tumor antigen.

124 (previously presented): The method of claim 117, wherein the systemic immune response is a protective systemic immune response.

125 (previously presented): The method of claim 117, further comprising delivering the polynucleotide with a device topically applied to the skin of the organism.

126 (previously presented): The method of claim 125, wherein the device includes a patch.

127 (previously presented): The method of claim 125, wherein the device includes an adhesive backing.

128 (previously presented): The method of claim 1, wherein the polynucleotide is complexed with an agent that promotes transfection.

129 (previously presented): The method of claim 128, wherein said agent is selected from the group consisting of cationic lipids, cationic phospholipids, quaternary ammonium lipids, cationic polymers, polyethyleneimines, cationic dendrimers, polyamides, polyamido-amines, calcium phosphate, DEAE-dextran, hexadimethrine bromide-DMSO, poly-ethylene and polypropylene glycols, polylysines, and combinations thereof.

130 (previously presented): The method of claim 129, wherein said agent is polyethyleneimine.

131 (previously presented): The method of claim 80, wherein the polynucleotide is complexed with an agent that promotes transfection.

132 (previously presented): The method of claim 131, wherein said agent is selected from the

group consisting of cationic lipids, cationic phospholipids, quaternary ammonium lipids, cationic polymers, polyethyleneimines, cationic dendrimers, polyamides, polyamido-amines, calcium phosphate, DEAE-dextran, hexadimethrine bromide-DMSO, poly-ethylene and polypropylene glycols, polylysines, and combinations thereof.

133 (previously presented): The method of claim 132, wherein said agent is polyethyleneimine.

134 (previously presented): The formulation of claim 93, wherein the polynucleotide is complexed with an agent that promotes transfection.

135 (previously presented): The formulation of claim 134, wherein said agent is selected from the group consisting of cationic lipids, cationic phospholipids, quaternary ammonium lipids, cationic polymers, polyethyleneimines, cationic dendrimers, polyamides, polyamido-amines, calcium phosphate, DEAE-dextran, hexadimethrine bromide-DMSO, poly-ethylene and polypropylene glycols, polylysines, and combinations thereof.

136 (previously presented): The formulation of claim 135, wherein said agent is polyethyleneimine.